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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,287	11/21/2003	Bruce A. Firestone	3123	3181
51957	7590	10/10/2007		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			EXAMINER OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/719,287	Applicant(s) FIRESTONE ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13-18, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 12 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response and terminal disclaimer, both received on 02 July 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-8, 10, 11, 13-18, 20 and 21 under 35 U.S.C. 103(a) over VESANOID (from the Physician's Desk Reference) in view of Cho *et al.* (U.S. Patent No. 5,656,289) is hereby withdrawn.

Claims 1-8, 10, 11, 13-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over VESANOID (from the Physician's Desk Reference) in view of Benita *et al.* (U.S. Patent No. 5,965,160)

VESANOID is a retinoid that is available from Roche Laboratories in 10 mg soft gelatin capsules for oral administration. Each capsule contains butyated hydroxyanisole, vegetable oils, and other additives. In addition, the capsule shell contains several well-known colorants that impart color and opacity such as red iron oxide, yellow iron oxide and titanium dioxide (See bottom of Page 2).

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VESANOID does not contain the specific additives as claimed by the applicant, such as the triglyceride or the specific emulsifiers.

The Benita *et al.* patent teaches self-emulsifying oily formulation comprising an oil component and a surfactant (See Abstract). The Benita *et al.* patent further teaches that the dosage form is particularly suitable for drugs with limited or no water solubility (See Column 1, Lines 34-43). The oil component may comprise a medium chain triglyceride such as Myglyol 812, which is a mixture of trimesters of glycerine and of caprylic and capric acids (See Column 4, Lines 51-58). The surfactant is preferably non-ionic and may be a combination of surfactants, such as Span 80 and Tween 80 (See Column 5, Lines 21-36). The disclosed formulation is typically provided within a capsule, which may further comprise an enteric coating, to allow for targeted delivery of the active agent (See Column 5, Lines 36-58).

One of ordinary skill in the art would have been motivated to combine the teachings of Benita *et al.* with the VESANOID formulation. The VESANOID formulation gives a specific orally administrable example of a drug that falls within the group of retinoids, which are traditionally known to be useful only in topical formulation. However, the VESANOID formulation teaches one very specific orally administrable capsule formulation comprising one specific retinoid. The Benita *et al.* patent teaches a generic formulation that can be used with many different drugs and may also be formulated into an enteric embodiment, so as to pass through the stomach without dissolving. One of ordinary skill in the art would have been motivated to look to a reference such as Benita *et al.* when formulating orally administrable capsules of a drug, specifically because Benita *et al.* teaches a vehicle for which a drug with low water solubility may be administered so as to increase its effectiveness. One of ordinary skill in

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the art would reasonably expect a successful pharmaceutical formulation that contains a retinoid and has enteric release properties to allow passage through the stomach. Therefore, the instantly claimed invention is prima facie obvious.

Double Patenting

The rejection of Claims 1-8, 10-18 and 20-22 on the ground of nonstatutory obviousness-type double patenting over Claims 1-24 of U.S. Patent No. 6,248,354 and Claims 1-9 of U.S. Patent No. 6,656,500 are hereby withdrawn in view of the terminal disclaimer filed 02 July 2007.

Claim Objections

Claims 12 and 22 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER